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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SHAFFER, RICHARD R

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/620,529

Applicant(s)

EISERMANN ET AL.

Examiner

Richard R. Shaffer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-50, 62-65 and 68-314 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-50, 62-65 and 68-314 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/30/2006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: DE 299 11 422 U 1.

DETAILED ACTION

Double Patenting

The Terminal Disclaimer filed on August 14th, 2006 has been approved. The previous double patenting rejections are overcome and hereby withdrawn.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41-50, 62-65 and 68-83 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-36 of copending Application No. 10/774,135 and claims 1-40 of copending Application No. 11/299,115. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending applications are more specific and are thus a "species" of the "generic" invention. It has been held that the generic invention is "anticipated" by the "species." See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the limitation of engaging a bone screw with the prosthetic joint and vertebra must be shown or the feature(s) canceled from the claims 77-80 and 83. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). The added claims copied from Marnay are replete with terminology without antecedent basis in the claims such as "sole implant" from claim 1 of Marnay '071. Correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 77-80 and 83 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. Claim 77 recites "a bone screw **engaged** between the intervertebral prosthetic joint and one of the first and second vertebrae to resist displacement of the intervertebral joint." Applicant is positively reciting a portion of the human body with the current language, it is recommended applicant words the claim such as "capable of being engaged," "engageable," or "for engaging."

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 79 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

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possession of the claimed invention. The only support applicant has in the specification is that a screw broadly engages to fix the prosthetic joint with a vertebra, not that the bone screw passes through the openings on the flanges. For examination purposes, no weight has been given to a bone screw having to be inserted into holes located in the flange, only that a bone screw is used to fix the implant to the vertebra.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 41-44, 73, 74, 76, 81, 82 and 84-314 are rejected under 35 U.S.C. 102(b) as being anticipated by Aesculap AG & Co. (DE 299 114 22 U 1).

Although the applicant is listed as the assignee, the patent is clearly that of Marnay et al as previously cited under WO 01/01893.

Aesculap discloses a device (**Figures 1-7**) comprising: a first bearing surface (**5**); a second bearing surface (**13**); a flange (**6**) projecting from the first bearing surface (**5**); a flange (**14**) projecting from the second bearing surface (**13**); the flanges (**6,14**) are centrally located and have a length that extends substantially entirely along the bearing surfaces (**5, 13**); the flanges (**6, 14**) having a width (the measurement taken vertically as shown in **Figure 2**) that tapers along the length with a beveled end (furthest edge/leading edge as shown in **Figure 2**); and a first articular surface (**12**) interfacing

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with a second articular surface (25) both located opposite the first and second bearing surfaces respectively.

It is noted that the device is inherently capable of being inserted in-between two vertebral bodies at any rotational sense such as at a lateral orientation.

In regard to claims 84-314, since applicant has copied claims from Marnay et al that merely claim their own invention, clearly the reference of Aesculap anticipates and discloses all of the claimed limitations.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 45-49, 62-64, 68-72 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aesculap in view of Michelson (US Patent 5,609,635).

Aesculap discloses all of the claimed limitations except for holes passing through the flange allowing for bone growth to enter and further comprising a bone growth substance to facilitate the bone growth. Michelson teaches (**Column 2, Lines 9-11; Lines 29-35; Column 6, Lines 56-66; Column 8, Lines 38-46**) that openings of random size, shape, and distribution passing partially or entirely through along with being composed or treated with materials for microscopic bone in-growth enhance stability of the implant within bone. It would have been obvious to one having ordinary skill in the art at the time the invention was made to create through holes as shown in

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Figure 1 of Michelson composed/treated with bone growth materials throughout the device of Aesculap in order to improve implant fixation.

Claims 50 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aesculap in view of Michelson and in further view of Gill et al (US Patent 6,113,637).

Aesculap in view of Michelson disclose all of the claimed limitations except for an indent on one of the articular surfaces. Gill et al teach (**Column 2, Lines 32-38; Column 6, Lines 31-64**) that an indent (52) provides translation between the two articular surfaces thereby avoiding jamming which in turn leads to wear provoking pain and/or accelerated degeneration. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide for an indent as taught by Gill et al to the combination of Aesculap and Michelson in order to avoid damage to the implant and/or pain to the subject.

Claims 77-80 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aesculap in view of Graham (US Patent 5,246,458).

Aesculap discloses all of the claimed limitations except for a bone screw that engages the implant and the vertebra. Graham teaches (**Column 2, Line 65 through Column 3, Line 2; Column 4, Lines 6-13**) screws being placed into members protruding into adjacent vertebral bodies in order to provide for a secure fixation of the implant within the spinal column. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide for screws to securely fix the

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flanges of Aesculap within adjacent vertebral bodies to maintain proper placement and orientation.

Claims 77-80 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aesculap in view of Ferree (US Patent 6,706,068).

Aesculap discloses all of the claimed limitations except for a bone screw that engages the implant and the vertebra. Ferree teaches (**Column 3, Lines 57-65**) that screws are used to fix the flanges of his implant (**Figure 4**) to the vertebrae. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide for holes in the flanges to allow for screws to pass through thereby fixing the implant in a fixed position and orientation relative to the vertebrae.

Response to Arguments

Applicant's arguments filed on August 14th, 2006 and August 30th, 2006 have been fully considered but they are not persuasive. Applicant alleges that Marnay (now applied Aesculap) only discloses a tapering height. There is no reason the height applicant refers to cannot be reasonably interpreted as the "width."

In response to applicant's argument that the limitation of anterior-posterior in terms of orientation of the device is not disclosed in Aesculap, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

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In response to applicant's arguments that the claims of Marnay are not supported by its own disclosure, applicant has failed to realize that the claims merely are reciting "comprising." Therefore, the device is not limited in regard to only a single flange on each side. It is merely required to have at least a single flange of the claimed limitations on each bearing surface, which is fully supported by the specification and drawings.

Applicant's arguments in respect to the remaining claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer
November 21st, 2006



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SUPERVISORY PATENT EXAMINER